



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,385	07/06/2001	Joyce A. Deleo	DC-0156	4729
26259	7590	09/21/2004		
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			EXAMINER JAGOE, DONNA A	
			ART UNIT 1614	PAPER NUMBER

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 February 2004 has been entered.

Claim 1 is pending.

Claims 2-7 have been cancelled.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Chamberlain et al. (Archives of Neurology).

The claim is drawn to a method of treating lower back pain with radiculopathy to an animal in need of treatment consisting of administering methotrexate to said animal at doses below 3mg/kg so that lower back pain with radiculopathy is reduced.

Chamberlain et al. teach administration of methotrexate to patients with

leptomeningeal metastases presenting with radiculopathy (see abstract). Methotrexate is administered intraventricularly in doses of 2 mg daily (total dose of 40 mg) (see page 508, column 1). Applicants' attention is directed to *Ex parte Novitski*, 26 USPQ2d 1389 (BOPA) illustrating anticipation resulting from inherent use, absent a haec verba recitation for such utility. In the instant application, the claims teach reducing lower back pain with radiculopathy consisting of treatment with methotrexate. Chamberlain et al. teach the same composition of methotrexate in the same dose (less than 3mg/kg) to be useful in treatment of leptomeningeal metastases with radiculopathy. It is now well settled law that administering compounds inherently possessing a protective utility anticipated claims directed to such protective use. In the administration of methotrexate for treatment of leptomeningeal metastases, the compounds would also inherently be treating the radiculopathy.

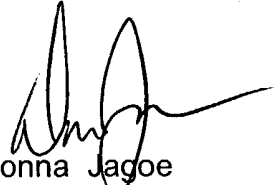
Because the prior art administers the same composition, methotrexate, it is reasonable and self-evident that methotrexate must treat the radiculopathy in each case, whether explicitly recognized or not.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 7:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe  
Patent Examiner  
Art Unit 1614

9/16/2004



CHRISTOPHER S. F. LOW  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600